

*What Every Member of the
Trade Community Should Know About:*

Wadding, Gauze Bandages, and Similar Articles (Heading 3005, HTSUS)



AN INFORMED COMPLIANCE PUBLICATION

JANUARY 2004

U.S. CUSTOMS and BORDER PROTECTION

NOTICE:

This publication is intended to provide guidance and information to the trade community. It reflects the position on or interpretation of the applicable laws or regulations by U.S. Customs and Border Protection (CBP) as of the date of publication, which is shown on the front cover. It does not in any way replace or supersede those laws or regulations. Only the latest official version of the laws or regulations is authoritative.

Publication History

First Issued April 2000
Reviewed with no Changes January 2004

PRINTING NOTE:

This publication was designed for electronic distribution via the CBP website (<http://www.cbp.gov>) and is being distributed in a variety of formats. It was originally set up in Microsoft Word97®. Pagination and margins in downloaded versions may vary depending upon which word processor or printer you use. If you wish to maintain the original settings, you may wish to download the .pdf version, which can then be printed using the freely available Adobe Acrobat Reader®.

PREFACE

On December 8, 1993, Title VI of the North American Free Trade Agreement Implementation Act (Pub. L. 103-182, 107 Stat. 2057), also known as the Customs Modernization or “Mod” Act, became effective. These provisions amended many sections of the Tariff Act of 1930 and related laws.

Two new concepts that emerge from the Mod Act are “***informed compliance***” and “***shared responsibility***,” which are premised on the idea that in order to maximize voluntary compliance with laws and regulations of U.S. Customs and Border Protection, the trade community needs to be clearly and completely informed of its legal obligations. Accordingly, the Mod Act imposes a greater obligation on CBP to provide the public with improved information concerning the trade community's rights and responsibilities under customs regulations and related laws. In addition, both the trade and U.S. Customs and Border Protection share responsibility for carrying out these requirements. For example, under Section 484 of the Tariff Act, as amended (19 U.S.C. 1484), the importer of record is responsible for using reasonable care to enter, classify and determine the value of imported merchandise and to provide any other information necessary to enable U.S. Customs and Border Protection to properly assess duties, collect accurate statistics, and determine whether other applicable legal requirements, if any, have been met. CBP is then responsible for fixing the final classification and value of the merchandise. An importer of record's failure to exercise reasonable care could delay release of the merchandise and, in some cases, could result in the imposition of penalties.

The Office of Regulations and Rulings (ORR) has been given a major role in meeting the informed compliance responsibilities of U.S. Customs and Border Protection. In order to provide information to the public, CBP has issued a series of informed compliance publications, and videos, on new or revised requirements, regulations or procedures, and a variety of classification and valuation issues.

This publication, prepared by the National Commodity Specialist Division, ORR, is wadding, gauze bandages and similar articles of Heading 3005, HTS. “Wadding, Gauze Bandages, and Similar Articles (Heading 3005, HTSUS)” provides guidance regarding the classification of imported merchandise. We sincerely hope that this material, together with seminars and increased access to rulings of U.S. Customs and Border Protection, will help the trade community to improve voluntary compliance with customs laws and to understand the relevant administrative processes.

The material in this publication is provided for general information purposes only. Because many complicated factors can be involved in customs issues, an importer may wish to obtain a ruling under Regulations of U.S. Customs and Border Protection, 19 C.F.R. Part 177, or to obtain advice from an expert who specializes in customs matters, for example, a licensed customs broker, attorney or consultant.

Comments and suggestions are welcomed and should be addressed to the Assistant Commissioner at the Office of Regulations and Rulings, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW, (Mint Annex), Washington, D.C. 20229.

Michael T. Schmitz,
Assistant Commissioner
Office of Regulations and Rulings

(This page intentionally left blank)

| | |
|--|-----------|
| INTRODUCTION..... | 7 |
| DEFINITIONS AND USES..... | 8 |
| MATERIALS | 11 |
| PHARMACEUTICAL SUBSTANCES | 13 |
| RETAIL PACKAGING, LABELING, FOLDING..... | 16 |
| POST-IMPORTATION MANIPULATIONS | 18 |
| PRODUCTS OUTSIDE THE PURVIEW OF HEADING 3005..... | 20 |
| POSSIBLE MISCLASSIFICATION CONSEQUENCES..... | 24 |
| THE IMPORTER’S RESPONSIBILITIES | 25 |
| INVOICE REQUIREMENTS | 25 |
| ADDITIONAL INFORMATION..... | 27 |
| The Internet..... | 27 |
| Customs Regulations | 27 |
| Customs Bulletin | 27 |
| Importing Into the United States..... | 28 |
| Informed Compliance Publications..... | 28 |
| Value Publications..... | 29 |
| “Your Comments are Important” | 30 |

(This page intentionally left blank)

INTRODUCTION

Heading 3005 of the Harmonized Tariff Schedule (HTS) appears straightforward enough at first glance. It provides for “[w]adding, gauze, bandages and similar articles (for example dressings, adhesive plasters, poultices) impregnated or coated with pharmaceutical substances or put up in forms or packings for retail sale for medical, surgical, dental or veterinary purposes.” All products classifiable in the provisions of the heading are statutorily free. We use adhesive bandages (e.g., Band-Aids®) in our homes. We have seen bandages of all types in pharmacies, gauze pads used by our physicians, and cotton wadding used by our dentists. It is all seemingly simple merchandise and all free of duty. Yet this has been an area of some difficulty. Brokers and importers classify many items in heading 3005 that do not belong there. As we shall see, the primary factors to consider for product classification in this heading are purpose (medical use - wound treatment), presence of pharmaceutical substances, and packing. This is important because failure of a product to meet the criteria required by the language of the heading may result in classification discrepancies, duty liability, and possible quota consequences.

Heading 3005 is divided into two subheadings: subheading 3005.10, which encompasses adhesive products, and subheading 3005.90, which encompasses nonadhesive products. Within each of those two subheadings a distinction is made between products coated or impregnated with pharmaceutical substances (i.e., subheadings 3005.10.1000 and 3005.90.1000) and products not coated or impregnated (i.e., subheadings 3005.10.5000 and 3005.90.50). That is the easy part! The difficulty is in understanding the parameters established by the language of heading 3005.

Since classification is initially determined according to the terms of the HTS headings, pursuant to Rule 1 of the General Rules of Interpretation, HTS, we must give close attention to the overall descriptive language of heading 3005. The first part of the heading speaks of wadding, gauze, bandages and “similar articles” such as dressings, adhesive plasters, and poultices. The concept of “similar articles” is subject to the rule of *ejusdem generis* (of the same kind or class). Similar goods are limited to those which “possess the essential characteristics or purposes that unite the articles enumerated *eo nomine*” [*Totes, Inc. v. U.S.*, 69 F.3d 495, 498 (Fed. Cir. 1995)].

Merchandise of heading 3005 is, first of all, wadding, gauze, bandages, dressings, adhesive plasters, poultices and the like. The second part of the heading then provides exact and limiting language for inclusion in the heading. Products must also be either coated or impregnated with pharmaceutical substances, or put up in forms or packings for retail sale. Additionally, in either case, articles of heading 3005 must be for medical, surgical, dental or veterinary purposes. These are the essential characteristics or purposes required of such products for classification in heading 3005.

It is our intention to first examine the general nature of the articles enumerated in heading 3005 and then look at the limiting language. We will provide definitions and examples of the exemplars and try to find their shared characteristics. We will then

discuss pharmaceutical coating and impregnation. Products treated with such substances will almost always be classifiable in heading 3005, so it is important to have an idea of what is meant by them. We will discuss products which are not coated or impregnated and examine what types of characteristics (e.g., folding, labeling, packaging, etc.) may be encountered in such products. We will then look at Customs' policy regarding allowable and non-allowable manipulations of "bandage-like" products after importation. Finally, we will provide examples of products often misclassified in the heading, and end with an overview of the possible consequences of misclassification.

DEFINITIONS AND USES

If we consult any medical dictionary, we find that all the examples given in the legal text of the heading, namely: bandages, wadding, gauze, dressings, adhesive plasters, poultices, etc., share the characteristic of being directly applicable to diseased or injured body tissue. This is reflected in the legal language of heading 3005, as well as in the Explanatory Notes (EN) to the heading, which constitute the official interpretation to the tariff at the international level. Thus, **the guiding principle is that the enumerated products are limited to materials used in the treatment of wounds in a medical, surgical, dental or veterinary setting.** We will now examine some common commercial conceptions of such articles.

Wadding is defined in the *PDR® Medical Dictionary, First Edition* as "[c]arded cotton or wool in sheets, used for surgical dressings." **Gauze** is a "bleached cotton cloth of plain weave, used for dressings, bandages, and absorbent sponges" (*PDR® Dictionary*). Surgical gauze or absorbent gauze USP must meet certain standards of purity, thread count, construction and sterility as described in the monograph on absorbent gauze in the *United States Pharmacopoeia*.

Wadding and gauze are thus general terms for materials used for surgical or wound dressings. These basic materials are often classified by their mesh (number of threads per inch), fiber length (for tensile strength), weight (in grams per square meter), or absorbency as required by a specific application. For example, some types of surgical dressings may require a closely woven gauze for extra strength or greater protection, while other wound dressings may require a more open weave for better absorbency or drainage.

Many products of heading 3005 are made of these cotton-based materials alone. Others are composite articles of cotton with other materials (such as plastic-film coatings or synthetic fibers such as Dacron® or rayon). Others are made completely of other materials such as oxidized cellulose (sterile gauze or cotton which has been chemically treated to make it hemostatic and absorbable), dried animal skin tissue, plastics such as vinyl copolymers, methacrylics, polyesters or rayons. Still others are impregnated or coated with pharmaceutical materials (such as petrolatum or oil/water emulsion) to render them less adherent to open wound surfaces. There are even liquid dressings, usually made of plastics in a solvent, which are sprayed onto the injured tissue area covering wounds with a protective film. The development of various types of

wound treatment products reflects the need to have products available that afford the greatest amount of protection and absorption while minimizing discomfort of the patient.

Like wadding and gauze, **dressing** is also a general term. We find that *Stedman's Medical Dictionary, 26th Edition (Stedman's)*, defines dressings as "the material applied...to a wound for protection, absorbence, drainage, etc." In *Dorland's Illustrated Medical Dictionary, 28th Edition (Dorland's)*, dressings are described as "any of various materials utilized for covering and protecting a wound." *Remington's Pharmaceutical Sciences, 18th Edition (Remington's)* defines surgical dressing as a term applied to a range of materials used for the dressing of wounds. There are various classes of dressings such as primary wound dressings, absorbents, bandages, surgical adhesive tapes and protectives. The following discussion is based on the discussion in *Remington's* found in the chapter on surgical supplies.

Primary wound dressings are applied directly to wound surfaces to help absorb the wound secretion and minimize maceration (unwanted softening of the tissue). Plain gauze compresses are rarely used nowadays because of their tendency to adhere to the wound. Specialized products have been developed which have a low degree of adherence. Stretchable cellulose with an oil/water emulsion is used for all types of wounds such as burns, skin grafts and open ulcers. Pads covered with soft plastic film having openings allow fluids to pass through while eliminating adhesion to the wound. Transparent films are not only nonadherent, but allow for examination of the wound without removal of the dressing.

Absorbents include open-mesh gauzes and surgical sponges made of nonwoven synthetic fabrics. These are more lint-free and more absorbent than cotton gauze sponges. Gauze strips with ravel-proof edges that eliminate all loose threads are ideal for use as packing strips in nose and sinus surgery as well as drainage wicks in the treatment of draining wounds such as boils and abscesses. Folded surgical pads or sponges, which may be unfolded to larger sizes without exposing cut edges or loose threads, are a standard part of operating room tray sets. Laparotomy sponges are used in surgical procedures to prevent abdominal or other organs from entering the field of operation. They are made of four layers of gauze, with the edges folded in and hemmed.

Bandages are "...piece[s] of cloth or other material, of varying shape and size, applied to a body part to make compression, absorb drainage, prevent motion, retain surgical dressings" (*Stedman's*). The function of a bandage is to hold a dressing in place by compression or support. Among the types of bandages available are rolls of absorbent gauze or muslin in continuous pieces. They may be cut as required. Muslin bandages are particularly strong and are used to hold bulky dressings or splints in place. Conforming or clinging bandages are made of specially processed gauze folded to the center. They conform to body parts and are self-clinging, thus preventing slippage. They are also used to hold dressings and splints in place. High-bulk bandages are made of up to six layers of crimped gauze and are designed to provide additional protective padding in wound dressing applications. Triangular bandages are

used to hold head dressings in place and can also be used in first-aid work as temporary splints for broken bones. Surgical stockinette bandages are made of stockinette material (an elastic, machine-made cloth) knitted or woven in tubular form. Their stretchability allows conformity to the arm, leg or body. They are used to cover and protect the skin prior to the application of a hard cast. These are typically sold in large rolls and cut to length as needed by a health care provider. Cast paddings are also applied to the skin under a cast to provide moisture absorption and allow the skin to breathe. Plaster coated fracture bandages must be included here as well, provided they are put up for retail sale for medical purposes (EN, heading 3005, p. 471).

Adhesive tapes are also included in heading 3005, **provided** they are impregnated or coated with pharmaceutical substances or are put up in forms or packings for retail sale for medical, surgical, dental or veterinary purposes [EN exclusionary item (a) to heading 5906, p. 897]. In such applications they are generally used to retain dressings. The primary concern in the use of such tapes is that they be hypoallergenic and nonocclusive, allowing the passage of excessive moisture away from the skin.

Protectives are used in conjunction with dressing materials to prevent loss of moisture or heat from a wound site. Film dressings are acrylate adhesives on a transparent, vapor-permeable plastic film applied directly to a wound surface. They are impervious to water and bacteria and are used to dress wounds which are already healing.

Stedman's and *Remington's* characterize **plasters**, or adhesive plasters, as solid preparations which can be spread when heated, and which become adhesive at the temperature of the body. They are used to keep wound edges in apposition, protect raw surfaces, and, when medicated, to redden or blister the skin (this is a counterirritant action to relieve symptoms of a deeper inflammation), or to apply drugs to a desired location.

Poultices are described as soft, moist masses prepared by wetting various powders or other absorbent substances with watery or oily fluids. They are sometimes medicated, and usually applied hot to the surface to create moist local heat or counterirritation. The classic poultices were spread on muslin, linen or other material. They were used to localize infectious material, and, when medicated, to supply a counterirritant effect, or exert an emollient effect upon a sore or inflamed part of the body by local application to the skin and underlying tissue surrounding the inflammation or sore (*Remington's*, *Stedman's*, *Oxford English Dictionary*, 2nd Ed.).

Compresses may be considered to be products similar to those enumerated in heading 3005. The *Oxford English Dictionary* defines a compress as follows: "[a] soft mass of linen, lint or other material formed into a pad, which by the aid of a bandage, can be made to press upon any part; used for compressing an artery, for keeping a dressing, plaister (sic), etc., in place, applying medical agents, and the like." *Webster's Third New International Dictionary Unabridged* offers two definitions of a compress: 1)

“a covering consisting usu. of a folded cloth that is applied and held firmly by the aid of a bandage over a wound dressing to prevent oozing;” 2) “a folded wet or dry cloth applied firmly to a part (as to allay inflammation).” The *Random House Unabridged Dictionary, 2nd Ed.*, describes a compress as “a soft, cloth pad held in place by a bandage and used to provide pressure or to supply moisture, cold, heat, or medication.” To be classifiable in heading 3005, a compress would have to be used in wound treatment, as, for example, a compression product used to treat venous ulcers. In such case, the compression serves to keep apposing wound edges together. Another example would be a gauze compress used as a primary wound dressing to absorb moisture, apply medication, etc.

Certain products provide support by compression for strained or sprained body parts (e.g., thoracic supports, hernia belts, elastic supports for wrists, knees and elbows, etc.). Other products serve to alleviate pain or reduce swelling by the delivery of heat or cold (e.g., heating pads, ice bags, eye masks, hot water bottles, etc.). While such articles may have application in medical or first-aid settings, they do not have the characteristics of the products of heading 3005, since they are not used in wound treatment. For a more complete discussion of compression products and articles used to deliver heat and cold, see the section entitled “Products Outside the Purview of Heading 3005.”

It appears clear from the foregoing definitions and concepts that the examples provided in the language of heading 3005 serve specialized functions in the field of health care. These functions are characterized by direct application to diseased or injured tissue, e.g., application to wounds for protection, immobilization, medication, etc. This is borne out by the definitions presented above. Products serving a lesser or different purpose, such as cleansing or soothing uninjured skin, are not classifiable in heading 3005. The basic requirement is that all these products must be for wound treatment in a medical, surgical, dental or veterinary setting, whether impregnated or coated with pharmaceuticals, or labeled, folded and packed for retail sale.

MATERIALS

The products defined above are basic, first-line materials used in the management of wounds. We will now focus on some of the materials making up these products. As we will see, different materials provide particular physical characteristics chosen for specific wound treatment and management needs.

The EN to heading 3005, p. 470, enumerate textiles, paper and plastic as examples of some of the materials encountered in products of that heading. In addition, the EN also include such specialty products as “cutaneous dressings,” comprised of dried animal skin tissue put up in sterile containers labeled with instructions for use, and “liquid dressings,” comprised of solutions of synthetic polymers with a propellant put up for retail sale in aerosol spray cans. There are dozens of wound care products on the market in the United States. We will look at some types and attempt to describe their

specialized functions. The physician, clinician, dentist, veterinarian or first-aid giver will select a particular product on the basis of the cause (e.g., burn, impact, cut), severity and location of the wound. Other products are utilized in more complicated applications, such as in skin graft or surgical procedures where immediate and rapid wound drainage, warmth, wound isolation, or surgical wall or organ protection may be of paramount importance.

Generally speaking, dressings are designed to optimize the immediate environment by providing a number of physical characteristics conducive to wound healing and maintenance. Depending on the severity of the wound, a dressing should provide a combination of any of the following characteristics: absorption or drainage of any wound exudate, occlusion to maintain a certain level of moisture (this has been found to help prevent later scarring), hydration to provide moisture, insulation to keep the wound warm and protect it from infectious agents, protection from physical harm, easy applicability and clean removal, odor reduction, wound visibility, etc.

The various available materials, sometimes in combination with topical pharmaceutical substances (see next section), must be chosen carefully by the clinician, physician, nurse, first-aid giver, etc., based on the extent and condition of the wound being treated. The following will provide some of the aforementioned qualities; all have certain advantages and disadvantages. We are listing them here with no intent of training the importer in wound treatment:

Gauzes: As previously noted, many bandage and dressing products are made of gauze. It affords many advantages, such as absorbability, good drainage, and easy use with topical pharmaceuticals and conformability. It has the disadvantage of needing frequent changing and sometimes “shedding” and adhering to the wound.

Foams: Foam dressings are made of nonadhesive polyurethane material. Products made of this material are absorptive, provide thermal insulation, maintain moisture, need to be changed less frequently, and are easy to remove without trauma. They are used in shallow wound treatment. They are not designed for deep wound or third-degree burn treatment.

Gels: Hydrogel dressings consisting of up to 95% water in sheets or gel forms are nonadherent, nonocclusive products with a high moisture content. They are used in treatment of wounds that have already begun to heal (with little exudate). They carry exudate away from the wound but retain it to provide a moist environment. They have advantages such as conformability, thermal insulation and easy removal. Gauze dressings are often impregnated with hydrogels.

Dextranomer: Dextran polymers specially prepared in small beads and available in unit dose packs are used to absorb dead tissue from around a secreting wound (such action is referred to as non-surgical debridement). Dextran beads are also poured over a wound to absorb exudate and prevent crust formation.

Films: Translucent dressings made of synthetic plastic materials help retain exudate over the wound, and are highly protective because they are impermeable to water and bacteria. A great advantage of this type of dressing is that the wound can be observed without constant dressing changes. Some special products even have a grid printed on the film so that the wound's progress can be monitored.

Alginates: Hydrophilic non-woven dressings are made of calcium or sodium alginate fibers. Alginates are derived from seaweed. Alginate dressing fibers are transformed into gel by wound exudate. These are useful in deep wound applications. They are absorptive, conformable, maintain a moist environment and are easily removed. Alginate dressings should not be confused with surgical or dental hemostats made of calcium alginate. Those are used in surgical procedures to stop bleeding and are eventually absorbed by the body (classifiable in heading 3006.10, HTS).

Hydrocolloids: These are composed of various natural (e.g., agar), semi-synthetic (e.g., modified cellulose) or synthetic (e.g., polyvinylpyrrolidone) materials. They are often in wafer form, with the hydrocolloidal particles contained in an adhesive form covered by a watertight film. These are used for all but the most severe wounds. They maintain exudate by particle swelling, maintain moisture, are impermeable to water and bacteria, provide thermal insulation, and provide immediate pain relief.

This is a list of some of the more common products. It is not intended to be all-inclusive. There are many other materials utilized. Whatever the material, it must be clear that the product be exclusively intended for medical uses, and be either impregnated or coated with pharmaceutical substances, or be in forms or packings for retail sale for use by the end-user.

PHARMACEUTICAL SUBSTANCES

Once it has been determined that a product has medical, surgical, dental or veterinary use, the next question is whether or not it is impregnated or coated with a pharmaceutical substance. Often a dressing or other product of heading 3005 will be coated or impregnated with a substance that provides additional chemical or physical characteristics important to the management of a wound. Such treatment may be considered a *de facto* indication that certain products are intended for medical uses. Therefore, the text of heading 3005 does not require that impregnated or coated products be packed or folded in any particular way. However, when considering such products, the importer must be aware that the mere presence of a pharmaceutical substance does not necessarily mean that the product is impregnated or coated with that particular material. For example, a barium sulfate radiopaque monofilament sewn or woven into a laparotomy sponge or a surgical towel is not considered an impregnation or a coating. The product must actually be physically impregnated or coated with the pharmaceutical substance. [HQ 952369 of 12/17/93, HQ 956806 of 11/1/94 and NY 885010 of 5/4/93.]

There is no clear definition of the term “pharmaceutical substances” in the HTS or in the EN. A few examples are given in the EN: counterirritants and antiseptics (EN to heading 3005, p. 470), and antibiotics (EN to heading 3802, p.557). General Note 13 to the HTS, which addresses the use of the Pharmaceutical Appendix to the Tariff Schedule, refers to pharmaceutical products listed in the Appendix as drugs. The EN to heading 1211, p.88, comes the closest to defining “pharmacy” for HTS purposes by stating that “...the broader term ‘pharmacy’ has reference both to medicaments and to products having no therapeutic or prophylactic uses...”

In dealing with heading 3005, CBP allows a broad concept of pharmaceutical substances. Therapeutic products such as drugs, as well as non-therapeutic substances such as water and oil emulsions, qualify as pharmaceutical substances. As long as the products of heading 3005 are impregnated or coated with these types of substances, they will be classifiable in subheadings 3005.10.10 or 3005.90.10. No other folding or packing will be required in such cases, but for the two exceptions described in the EN to heading 3005, namely: products covered with zinc oxide and plaster-coated fracture bandages. Such products **must** be packed for retail sale to be classifiable in heading 3005 (EN, p. 471). Otherwise, impregnated or coated products do not have to be packed or folded or labeled in any particular way as long as they are used for medical, surgical, dental or veterinary purposes.

There are numerous pharmaceutical products found in bandage and dressing-like products of heading 3005. Generally, such substances will perform a subordinate, but necessary, function in the product’s application to the wound. Sometimes the function of the pharmaceutical will be of paramount importance. Pharmaceutical substances may assist in protecting tissue or alleviating tissue irritation (e.g., oil/water emulsions, ointments, demulcents, humectants, emollients, astringents, counterirritants, etc.), provide extra absorbency for wound drainage or keeping skin free of excess moisture during healing (absorbents, protectives), provide antiseptic action for the immediate wound area (iodoform, povidone-iodine, isopropyl alcohol, antibiotics), alleviate or manage pain (local anesthetics, corticosteroids), deodorize the wound area (activated charcoal), act as non-surgical debriders to clear away dead tissue during healing (enzymes), etc.

In all probability, the most common type of pharmaceutical substance with which dressing or bandage materials are impregnated or coated is the **antiseptic**. This would include *inter alia* iodoform, povidone-iodine, iodine, bactine, benzalkonium chloride, silver sulfadiazine, hexylresorcinol, salicylic acid, 1% glacial acetic acid solution, bismuth tribromophenate, 8-hydroxyquinoline, diluted acetic acid, isopropyl alcohol, and ethanol. The last two products have mild antiseptic actions at 70% concentrations and higher. If a product containing these alcohols were indicated merely for cleansing unbroken skin, that product would not be considered classifiable in heading 3005. [HQ 953256 of 6/9/93.] Generally, antiseptics would be used to enhance the protective quality of a dressing by further reducing the bacteria count at a wound site.

Antibiotics would serve a purpose similar to that of antiseptics. The topical use of antibiotics for bacterial count reduction in wound treatment is limited to non-systemic antibiotics such as polymixin B, bacitracin, neomycin, gramicidin, and nystatin. They are often formulated with other pharmaceuticals such as hormones and local anesthetics in combination creams, ointments and powders.

Topical agents include substances that act physically as well as chemically on skin tissue. Such products work in various ways to insulate or protect the skin from external factors (bacteria etc.), provide adsorbency, provide mechanical support, act as carriers for medicaments, alleviate irritation, act as counterirritants, soften and/or moisturize the skin, etc. Such agents include protectives, such as zinc gelatin and white petrolatum; absorbent-moisturizers, such as hydrogels; adsorbents, such as kaolin; odor absorbents, such as carbon; astringents, such as aluminum acetate topical solution and zinc oxide; local anesthetics, such as lidocaine; keratolytics, such as salicylic acid (which is also antiseptic); chemical debriders, such as enzymes and dextran polymer; and various ointment bases, such as oil/water emulsions, polyethylene glycol ointment, etc., which are designed to act both as emollients and drug delivery facilitators.

More often than not, the foregoing products would be separately applied to a wound area and then covered by a dressing and/or bandage product. However, there are numerous products on the market which are impregnated or coated with such materials. A dressing product intended for use in the medical, surgical, dental or veterinary fields will most likely not contain anything but a “pharmaceutical substance” which meets the requirements of the *United States Pharmacopoeia* (USP). It should also be noted that these types of products are designed for local application, treating only the immediately injured or diseased tissue.

There is a group of products called **transdermal delivery systems** that are designed for the systemic delivery of drugs. Such products are not classifiable in heading 3005. Transdermal delivery systems are differentiated from products of heading 3005 in a number of ways. They may appear at first glance to resemble adhesive patches containing a medicament, but are actually more highly engineered. They often consist of a backing, a well or reservoir containing a drug substance, which is released in a timed fashion through a properly chosen control membrane, an adhesive layer, and a protective layer. The intent is to deliver the drug through the vascular system of the skin to the desired internal organ. The result is that the drug is treating a condition systemically, rather than locally. A transdermal system may be applied anywhere on the body. Products of heading 3005, as we have seen, are applied locally for local action.

Examples of transdermal systems are nitroglycerin (for the treatment of angina) in disks applied to the upper chest or arm, scopolamine (for the treatment of nausea) applied behind the ear in a polymer device, clonidine (an antihypertensive drug) in a multilayered film, and estradiol (to treat various symptoms and conditions associated with menopause) in a multilayered system. [See **HQ 961177** and **HQ 961666**, both of

4/14/98.] All of these products are classifiable as measured dosage forms of medicaments in various subheadings of heading 3004, HTS, not in heading 3005. However, patches containing chemical contraceptives are classifiable in subheading 3006.60.0000 by virtue of HTS Chapter 30 Note 4(h).

RETAIL PACKAGING, LABELING, FOLDING

When describing wadding and gauze for dressings and bandages *not* impregnated or coated with pharmaceutical substances, the EN to heading 3005 speak of labels affixed or special folding as being indicative of intended use for surgical, medical, dental, or veterinary purposes (EN, p. 470). The heading language and EN (p. 470) also state, as we have seen, that such products must be for direct sale, **without repackaging**, to users (private persons, hospitals, etc.). In this section, we will survey some of the typical labels; folding and packages often encountered in these products. In the next section we will look more closely at post-importation manipulations.

The Federal Food, Drug, and Cosmetic Act (FFDCA) and amendments thereto designates the *United States Pharmacopoeia* (USP) and the *National Formulary* (NF) as official compendia for drug and pharmaceutical products in the United States. The law recognizes USP and NF standards as guidelines for determining the identity, strength, quality and purity of the articles. These standards also establish specifications for labeling and packaging. In addition to the legal recognition, USP and NF standards play an important role in ordinary industry and commercial transactions.

Surgical and medical dressings and related products must generally meet the requirements of the USP for a number of specific characteristics, namely: material content, absorbency, fiber length and width, weight, thread count, solubility, adhesive strength, tensile strength, ignited residue, acidity or alkalinity, fatty matter, alcohol-soluble dyes, sterility, labeling, packaging and storage. Some of these requirements may be stated on labels affixed to these products. The presence of such labels is one of the indications the CBP officer or importer may rely on in determining the proper classification of such articles.

The USP monographs on dressings and bandages have specific language concerning thread count, layers, labeling and packaging. For example, the USP monograph regarding the labeling of absorbent gauze states: "Its type or thread count, length, and width, and the number of pieces contained, are stated on the container, and the designation 'non-sterilized' or 'not sterilized' appears prominently thereon unless the Gauze has been rendered sterile, in which case it may be labeled to indicate that it is sterile. The package label of sterile Gauze indicates that the contents may not be sterile if the package bears evidence of damage or has been previously opened." The labeling requirements are similar for many such products. Sterile products should be marked as such and packaged in such a way as to maintain sterility. A typical USP monograph will state as much. For example, the monograph on absorbable gelatin film reads as follows: "Preserve in a hermetically sealed or other suitable container in such a manner that the sterility of the product is maintained until the product is opened for use."

Many products are folded to provide ease of use or specialized application. Surgical gauze pads or sponges are folded so that no cut edges are exposed. They are further folded so that a smaller size pad may be opened to a larger size without exposing any cut edge or loose threads. This helps reduce shedding or fraying and adhesion to the wound. The pad or sponge or dressing may be available in various layers (e.g., 8-, 12-, 16-, 24-ply) for specific jobs. Laparotomy sponges are usually 4 layers of 28x24 mesh gauze, folded toward the center and hemmed. Conforming bandages are made of 2-ply, high quality, 14x8 cotton gauze, folded toward the middle.

The lesson to be learned from such examples is that products of heading 3005 will often clearly be designed, labeled, folded, packed, and sterilized for direct medical uses. Folding, labeling and sterilization are not requirements, just illustrative of certain intended applications. Definite use for medical purposes may be established by the presence of accompanying literature, labeling, presentation, sterilization, protective coverings, and instructions for use and storage. Such factors, though not compulsory or decisive, may help establish exclusive intent for use for medical purposes, and for direct sale to end-users.

Products not clearly packaged, labeled or folded for direct medical use may or may not be classifiable in the heading. The intended use and the intended end-user must be established and identified. Furthermore, in the context of the EN to heading 3005, “retail” sale is not limited to sales by retailers, only to retail customers or users; it means sales directly- without repacking- to end-users, whether individuals or institutions such as hospitals (EN, p. 470).

Customs Headquarters, in **HQ 953499** of 4/6/93, held that cotton bandage rolls sold to hospitals and nursing homes in cartons of 100 were classifiable in heading 3005. In this case, the importer declared there was no intention of repacking the bandages and that the medical institutions used the bandages in such quantities as to justify bulk purchases. By establishing the bulk sale to be for direct use by the hospital (i.e., the end-user), and that no repacking would take place after importation, the importer was able to satisfy the conditions required by the legal language of and the EN to heading 3005.

Imported materials, such as continuous rolls of wadding or gauze fabric in the piece, manufactured into bandage or dressing products and then packed for retail sale **subsequent** to importation are **not** classifiable in heading 3005. In such instances, since such products lack the characteristics enumerated above (i.e., retail packing, cutting, special folding or labeling), there would be no evidence to establish that they are, in fact, “exclusively intended. . . for sale directly without re-packing to end-users. . . for use for medical, surgical, dental or veterinary purposes” (EN, p.470). Classification of such products would then be based on the actual composition of the material. Possible classifications outside of heading 3005 will be briefly discussed in the section below entitled “Possible Misclassification Consequences.”

POST-IMPORTATION MANIPULATIONS

As we have seen in the preceding section, when dealing with products not impregnated or coated with pharmaceutical substances, there are usually indicators present, e.g., packing, folding, labeling, etc., which may help establish compliance with the requirement for direct sale without repacking to the end-user for exclusive medical, surgical, dental or veterinary use. **Such indicators must be present in the products in their condition as imported. Manipulations after importation, such as repacking, labeling or relabeling, special folding, etc. will render the products ineligible for classification in heading 3005.** This principle is enunciated in the EN, p. 470: repacking for retail sale after importation is not allowed, no matter what other manipulation takes place. This is an extension of the legal language of the heading, which requires that products of heading 3005, which are not impregnated or coated with pharmaceutical substances, be “put up in forms or packings for retail sale for medical, surgical, dental or veterinary purposes.” First of all, to be classified in heading 3005, these articles must be imported in retail packing and be exclusively intended for direct sale to end-users. Second, such articles must be specifically intended for medical purposes. We have seen that labels, folding, accompanying instructions, and sometimes sterilization may be indicative of medical use. If such indicators are not there, or if they are added after importation, classification in heading 3005 may be precluded.

With regard to heading 3005, the concept of repacking is most critical. Customs Headquarters has been consistent and clear in its position: an imported product that is neither impregnated nor coated with a pharmaceutical substance must be packed in a manner requiring no further specialized packing for retail sale.

In **HQ 959053** of 11/19/96, we find that a product imported in bulk and then repacked or put up in a *different* form or package for retail is not classifiable in heading 3005. In that ruling, laparotomy sponges were imported already cut to size, sewn to specific dimensions, and bundled together in packs of five with a paper band. Each sponge contained an x-ray detectable strip (treated with barium sulfate) which was sewn into the sponge. After importation, the importer shipped the sponges to two offsite pre-sterilization plants. The pre-sterilization was accomplished by either gamma radiation or steaming, without the sponges being removed from the original shipping cartons. The cartons were then returned to the importer. After this pre-sterilization process, the importer removed all the sponge bundles from the shipping cartons and encased them in either a two-piece sealed pouch or two-piece sealed plastic tray. The pouches and trays were labeled with the required label information. The importer stated that the repacking into pouches and trays was strictly for final sterilization purposes. The encased products were then placed in outer, gas-permeable, shipping cartons for final sterilization. The final sterilization process was not described. The importer claimed that, during all this processing, the sponges were never removed from the five-pack bundles and never refolded or otherwise changed. The importer held that the original folding and bundling were sufficient to establish importation in a form for retail sale.

In disagreeing with the importer's claims, Customs Headquarters emphasized that, despite the presence of folding and bundling, the transfer of the sponges to trays or pouches is a separate packing operation required before retail sale. The heading language requires that products be put up in forms or packing for retail sale, i.e., already in retail packaging ready for sale for medical uses. The EN further explains that that means the products are not to be repacked before retail sale. "Forms for retail sale" does not refer to special folding or the like. Folding by itself is only a possible indication of special medical use. The requirement is for packaging, which clearly indicates intent for medical uses at the retail or end-user level.

In **HQ 952369** of 12/17/93, cotton gauze sponges specially folded, and containing radiopaque strips, were banded together in bundles of ten and imported in bags containing up to 4000 sponges. After importation, they were placed in trays with fold-over labels and sterilized. In this instance, Customs Headquarters ruled that, since the sponges had to be repacked after importation before sale to the actual users, they were not classifiable in heading 3005. Similarly, in **HQ 956806** of 11/1/94, Customs Headquarters ruled on laparotomy sponges folded and sewn around the edges, with an x-ray element sewn in. The sponges were banded together in groups of five, labeled and placed in cartons of 700 5-sponge packages. Subsequent to importation, the laparotomy sponges were placed in plastic trays and sterilized. Once again, Headquarters concluded that repackaging for sale to the end-users after importation precluded classification in heading 3005.

The EN language is such that any repackaging for final retail sale prevents a given product from being classified in 3005, even if that repackaging does not alter the product itself in terms of physical characteristics such as size, weight, composition, labels and folding. These characteristics may aid in determining whether or not a product is intended for medical uses. By themselves they may indicate a certain intention for use. However, the EN provides that the product still must be imported in packages exclusively intended for such use for direct sale to the actual user. There can be no intent to repack after importation. The importers' customers must be considered here. Are the customers end-users (private persons, physicians, hospitals, clinics), retailers (drug stores), wholesalers, or repackers? If the customers are repackers, it may indicate that there was no exclusive intent to sell directly to end-users without repackaging. **HQ 958285** of 11/22/96 addresses these issues in detail, although the exact nature of the repackaging in that ruling is not articulated.

We have seen that a product imported in bulk, then unpacked, labeled and repacked after importation, will not be classifiable in heading 3005, even if it is already in a condition or form (e.g., folded and sewn) that would permit it to be shipped for direct sale. If, **before** importation, a product is folded, sewn, equipped with an x-ray detection strip, bundled in groups, banded, over-wrapped, placed in bags or trays, packed in shipping cartons, and sterilized, it **is** classifiable in heading 3005 [**HQ 085962** of 3/2/90].

Customs' position is one of strict interpretation of the EN, **but it is limited to repacking or significant manipulation of the immediate package.** In other words, if an importer imports a product already in a form or packing for retail sale (e.g., individually packed and labeled gauze sponges), sterilizes it in that original packing and then packs it in a different outer shipping carton, that product remains classifiable in heading 3005. The product is already individually put up in an immediate container or packing for retail sale and intended for medical use. In such a case, sterilization is merely a further indication of the intended use of the product. [NY 853634 of 6/29/90 and HQ 959053 of 11/19/96.] Products already put up in forms or packings for retail sale (e.g., a bandage roll packed and labeled, Band-Aids® packed in their immediate retail packaging material) and imported in shipping cartons, may be repacked into smaller shipping cartons and still be classifiable in heading 3005. Breaking down shipping cartons of retail product into smaller lots is not a significant repackaging operation. Such an operation would not affect the immediate retail packaging of the product. **The language of heading 3005 does not require that an importer sell only to a retail user, only that an imported product be in a form or packing for retail sale for medical purposes. It is only manipulations that require repackaging of the immediate retail package that are not allowed.**

PRODUCTS OUTSIDE THE PURVIEW OF HEADING 3005

Aside from the preceding post-importation manipulations, are there any other factors or product characteristics that would preclude a given item from classification in heading 3005? In the section above on pharmaceutical substances, we discussed the characteristics of transdermal drug delivery systems. We saw that those products were not to be classified in heading 3005. In 1999, Customs revoked a number of ruling letters issued on various other products previously classified in heading 3005. These products also did not meet the requirements of the heading language. As we have seen, products of this heading must be utilized in the various aspects of wound treatment in a medical, surgical, dental or veterinary setting. **Articles not rising to the level of medical treatment are not classifiable in the heading.**

Among the products previously classified in heading 3005 were bags of fabric filled with various vegetable matter (cherry pits, flax seed, oatmeal, rice) and/or aromatic components (lavender seeds, peppermint leaves). Also included were eye masks filled with colored water and glycerol, magnetic "therapy" products (strips of adhesive tape with magnets attached), huggable bunny rabbit pillows, cute frog pillows, and hot and cold packs which could be frozen or heated. These products all offered some type of stress relief, comfort from everyday woes, soothing relief from aches and pains, new energy or vitality, or other tonic uses. Not one of them was intended for use in the treatment of wounds in an actual medical setting. They were not of a class or kind of product encompassed by the language of heading 3005. There were dozens of rulings in effect classifying such products in heading 3005 until 1999, when Customs Headquarters issued and posted revocations in the *Customs Bulletin* on a number of them. In posting those revocations, Customs Headquarters announced that the

revocations covered any rulings on similar merchandise that may exist but were not specifically identified.

The ruling letters discussed in the following paragraphs cover a wide range of products no longer classifiable in heading 3005. Importers of substantially identical merchandise should be guided accordingly.

HQ 962611 of 5/4/99 overturned **NY A85858** of 6/25/96. The “SUPER BAN Massage Patch” consisted of an adhesive patch on a release-paper backing. Each patch was 7/8” x 7/8”, had four ventilation holes, and contained a small, round ferrite magnet attached at the center of the patch. The product was to be applied directly to the skin to relieve “tightness” and to promote circulation in the local area. Customs Headquarters ruled that such a product was not of a class or kind possessing the characteristic of articles enumerated in heading 3005. Such articles must be directly applicable to an open wound or irritated (e.g., by infection) skin. It was held that the heading is limited to items used for actual medical purposes. The relief of tightness and circulation improvement claimed to be provided by the “SUPER BAN” product did not rise to the level of medical treatment. **HQ 962612** of 5/4/99 overturned **NY A83573** of 5/12/96. The product in that ruling, “Magnetty 1000,” was a variation on the “SUPER BAN” theme: a small magnet on an adhesive patch generated a magnetic field which improved circulation, thus relieving pain, soreness or stiffness. Again, this product was not used for wound treatment. Its pain relief claim did not rise to the level of medical use. These goods were found to be composite articles classifiable in heading 8505 according to the component (the ferrite magnet) which gave them their essential character (operation of General Rule of Interpretation 3(b)).

HQ 962352 of 2/11/99 modified **NY 806312** of 2/16/95. In the New York ruling, “Cool Paks” were classified in heading 3005. These were various sizes of rectangular pads made of polyacrylamide crystals enclosed within woven fabric. When soaked in water, the crystals absorb the liquid and expand to many times their original size. The pads are then placed against the skin. The coolness of the absorbed water and the action of evaporation of moisture from the skin bring about a cooling effect. Alternately, the product may be warmed in a microwave oven and used to provide heat treatment to an area of the body. In revoking this ruling, Customs Headquarters again found that the product was intended to provide a degree of comfort, but was not of a kind used to treat a wound. The intended use did not rise to the level of medical purposes. Final classification, in heading 3926, was based on the component (the polyacrylamide crystals) which imparted the essential character to the article.

HQ 962310 of 4/13/99 revoked **NY B86429** of 6/23/97. A flaxseed eye mask, “Sobakawa Pillow,” consisted of a small, sealed pouch of woven fabric filled with flaxseeds. Accompanying instructions indicated that the product should be placed across the bridge of the nose and over the eyes to soothe tired eyes. The product could also be placed in a freezer prior to application. Customs Headquarters held that soothing the eyes was not a characteristic of products enumerated in heading 3005 and that the tonic effect did not rise to the level of medical use.

HQ 961089 of 4/13/99 revoked **NY A83830** of 5/31/96. “PitPacs” heating and cooling pads consisted of cherry pits encased in a cotton bag. The instructional literature indicated that these bags could be heated in a microwave oven, standard oven, or double boiler, or cooled in a freezer. In the heated or cooled state the bags could be applied to the body to reduce tension, aches and pains. This use was held to be of a general tonic nature, and the product could not be considered to have a definable medical purpose.

In **HQ 962353** of 4/13/99, revoking **NY 813748** of 8/14/95, a “Magic Bag” contained cereal (oat) grains in a cotton bag. These bags were also designed to be heated or cooled as instructed. They were to be used on the body to reduce swelling and relieve aches and pains. This use was found not to be similar to that of products classifiable in heading 3005. Reduction of aches and pains was also not considered a medical application.

The “Sobakawa Pillow,” the “PitPacs,” and the “Magic Bag,” were all reclassified according to the components imparting the essential character to the articles. In these cases, those components were the vegetable products (flaxseed, cherry pits, and oats). Classification was in heading 1404.

An importer of similar merchandise must be prepared to submit to Customs a compositional breakdown by weight, as well as a material breakdown by value, of all the components of the product. Additionally, samples and instruction for use should be made available to the Customs officer examining the merchandise for classification.

We have seen that the preceding products not only do not belong to the same class or kind of merchandise as heading 3005 exemplars, but that they also have no true medical uses. However, there are other products intended for medical or first-aid applications that nevertheless do not belong to the class or kind of merchandise envisioned by the legal language of heading 3005. In the following paragraphs, we will discuss compression products, triangular bandages, elastic bandages, and cotton swabs. The intent is to examine if and how such products may differ from those of heading 3005. Importers of such products should seek classification advice from US Customs and Border Protection. A full discussion of classifications outside of heading 3005 is not within the purview of this publication.

As a reminder, a bandage is essentially a piece of material applied to a body part to make compression, absorb drainage, prevent motion, or retain surgical dressings. To this medical dictionary definition we may add the concept of lending support to an injured area [**HQ 953990** of 8/2/93]. When does such a product remain classifiable in heading 3005 and when does it not?

In the previous section on “**Definitions and Uses**,” we mentioned tubular bandages, made of stockinette material, and triangular bandages, which have a number of medical uses, as being classifiable in heading 3005. Woven or knitted stockinette

tubular bandages are sometimes used as a protective covering for irritated skin before a cast is applied to a broken limb. They are also used as compresses in the treatment of edemas. When packaged for retail for such uses, these have been classified in heading 3005 [**HQ 952343** and **HQ 952769**, both of 10/22/92).

Items that exclusively lend support to body parts are not classifiable in heading 3005. Stockings for varicose veins, suspensory bandages, supporting belts, athletic supporters, maternity belts, thoracic support bandages, abdominal support bandages, and supports for wrists, knees and elbows are *not* items belonging to the class or kind of items enumerated in heading 3005. Some of these products may be described as compression articles and be rated (in millimeters of mercury) for compression. Some of these products may even be called “bandages” (certain washable, reusable elastic bandages), but they are not designed for use as dressings, bandages, etc. as defined. They are not used to treat wounds. They do not act as compresses applied to wounds. They do not immobilize body parts in order to help in wound healing. They are strictly utilized to help support muscles and joints during the course of normal or athletic activity. The elasticity of such products makes them ideal for supporting sprains because they allow limited motion and stretching in case of swelling so that circulation is not impaired. If their intended supportive effect derives solely from their elasticity, they are classifiable in subheadings of Section XI HTS (“Textiles and Textile Articles”) according to composition and design [Chapter 90, Note 1(b)].

Orthopedic articles are also not classifiable in heading 3005. This would include any appliances used to correct or compensate for bodily deformities such as trusses, and splints and fracture appliances used to immobilize injured body parts or assist in setting fractures. Such articles would include plaster bandage splints used in conjunction with a fracture bandage to add rigidity to a cast. Such articles are generally classifiable in heading 9021. However, fracture bandages themselves are not appliances. They are often presented in rolls and made of bandage materials such as gauze impregnated with plaster of Paris, or of polyester cotton or fiberglass. They are used as casting materials in forming casts. They are applied wet or softened to the fractured limb and allowed to dry to form casts of varying degrees of hardness, rigidity, water-resistance, and durability. Hard splints may be applied during the application of such bandages for added strength and support. These types of casting bandages *are* classifiable in heading 3005, but splints are not.

Triangular bandages used in first-aid work as head wound dressings, temporary slings for immobilization, and temporary splints for broken bones, are classifiable in heading 3005, as long as they serve such general medical purposes and are packed for such use([**NY 832671** of 12/6/88 and **NY 838151** of 3/23/89). Such bandages are usually made of cotton cloth. They can be cut to various sizes. To remain classifiable in the heading, they should have the characteristics of a bandage and not of a specially designed article to be used, e.g., exclusively as a splint or immobilizing limb holder. They should be of a weight suitable for a bandage, light enough to allow for easy wrapping around the head or other injured body part. Heavy, less pliable materials

would indicate use only as a sling. The addition of grommets, strings, reinforced parts, rigid pieces of plastic or fabric, etc. would also indicate a special application more in the nature of a fracture appliance than a bandage (**NY E82352** of 5/21/99). A triangular bandage imported together with a rigid splint would also indicate a more specialized product than a general bandage.

Cotton swabs, whether of general or specialized use, have been consistently determined to be classifiable outside of heading 3005 (**HQ 953256** of 6/9/93 and **NY 881943** of 1/26/93). They are not similar to the exemplars of heading 3005. Swabs are generally of unwoven material not suitable for wound dressing or treatment. In a medical setting, they are used for no more than possible cleansing of or application of an antiseptic to unbroken skin, and not for dressing wounds. When importing merchandise of this nature, the importer should be prepared to submit samples, instructional, technical and advertising literature, and compositional breakdowns by weight.

POSSIBLE MISCLASSIFICATION CONSEQUENCES

Misunderstanding or misapplication of the principles of classification for heading 3005 may have duty and quota implications. The legal notes and Explanatory Notes to other chapters and sections of the HTS contain numerous cross-references to the products of heading 3005. For example, HTS Section XI (covering textiles and textile articles) Note 1(e) states that the Section does not cover articles of heading 3005 such as wadding, gauze, bandages and similar articles for medical, surgical, dental or veterinary purposes. Throughout the EN to the headings of Section XI there are exclusionary statements referring to heading 3005. Similarly, there are exclusions in certain headings of Sections X and XIII.

When a product is deemed not classifiable in heading 3005, it will become classifiable elsewhere in the tariff depending upon its composition and construction. Products made of textiles may end up being classified as carded or combed wool (headings 5111 and 5112), various cotton textile products, including woven products (Chapter 52), vegetable textile products (Chapter 53), woven fabrics of man-made fibers (headings 5407 and 5408), fabrics of man-made staple fibers (headings 5512-5516), wadding or nonwoven fabric (headings 5601 and 5603), gauze or narrow woven fabrics (headings 5803 and 5806), rubberized textile fabrics or other (non-pharmaceutically) impregnated textile fabrics (headings 5906 and 5907), or certain knitted fabrics (heading 6002). This list is not all-inclusive. Many Section XI products are dutiable, as opposed to the products of heading 3005, and may also fall into textile categories subject to the quota and visa requirements for such products.

Section X covers paper and paper products. Certain products otherwise classifiable in heading 3005 may be classified in Section X if they are found not to comply with the requirements of heading 3005. Some may be classified in heading 4803 as cellulose wadding, in heading 4811 as paper or cellulose wadding coated or impregnated with, e.g., plastic, or in heading 4818 as certain household or hospital

articles. Section XIII, heading 6809, covers articles of plaster. Plaster-coated fracture bandages put up for retail sale are classifiable in heading 3005 (see the previous section); those not put up for retail sale are potentially classifiable in heading 6809. Most products of these headings are dutiable.

THE IMPORTER'S RESPONSIBILITIES

Since the enactment of the Customs Modernization Act in December, 1993, the legal burden of correctly classifying merchandise has shifted from US Customs and Border Protection to the importer, who must use reasonable care in carrying out this responsibility. Prior to importation, the importer of record is responsible for determining the nature, material composition, packing, and intended use of the merchandise in its condition as imported.

The importer of bandages, dressings and similar products of heading 3005 should be aware of the limiting language requirements of the heading. The prospective importer should be familiar with the definitions and other classification issues and principles contained in this publication. If an article does not belong to the class or kind of merchandise used for wound treatment, or is not packed as required, classification outside of heading 3005 is probable. Should a product be made of textile materials, the importer should be aware of the possibility that the product may be subject to quota restrictions and should be prepared to furnish a proper visa if required.

Prior to the importation of a particular bandage or bandage-like article, an importer or a foreign supplier who wishes to verify the classification of the product may request a binding ruling from US Customs and Border Protection. See Part 177 of the Customs Regulations (19 CFR 177). When requesting such a ruling, the inquirer should submit a sample, marketing literature, use instructions, a description of any post-importation manipulations, including possible repackaging, and composition by weight and value of the component materials.

INVOICE REQUIREMENTS

In accordance with Section 141.86 of the Customs Regulations (19 CFR 141.86), certain general invoice information is required at the time of entry or entry summary. While Title VI, Subpart B, Section 636 of the Customs Modernization Act (Mod Act) has permitted some latitude in the application of Section 141.86, invoice information and descriptions must be sufficient for the CBP Officer to determine admissibility and verify classification and value of the imported merchandise. If invoice information is insufficient to resolve questions of admissibility or public health and safety, merchandise may be detained and entries may be rejected. If an invoiced merchandise description is found to be insufficient for classification or appraisement verification, the Port Director retains the option of requesting additional information by issuance of a Customs Form 28, a telephone call, or an importer interview. The importer of record is accountable for the veracity of the information supplied in any invoice or supplemental documentation.

In the case of merchandise potentially classifiable in heading 3005, it would be helpful to include in the merchandise description the exact trade name (if applicable), whether or not it is an adhesive product, unit packing information (including sizes, thread counts, measurements, etc.), and composition (including any materials with which the merchandise may be impregnated). If such information is not included, the Port Director may request it (along with samples if needed). In the case of merchandise made of textile materials, additional information for certain classes of textile merchandise (such as cotton or man-made fabrics) should be included as required by various sections of 19 CFR 141.89.

ADDITIONAL INFORMATION

The Internet

The home page of U.S. Customs and Border Protection on the Internet's World Wide Web, provides the trade community with current, relevant information regarding CBP operations and items of special interest. The site posts information -- which includes proposed regulations, news releases, publications and notices, etc. -- that can be searched, read on-line, printed or downloaded to your personal computer. The web site was established as a trade-friendly mechanism to assist the importing and exporting community. The web site also links to the home pages of many other agencies whose importing or exporting regulations that U.S. Customs and Border Protection helps to enforce. The web site also contains a wealth of information of interest to a broader public than the trade community. For instance, on June 20, 2001, CBP launched the "Know Before You Go" publication and traveler awareness campaign designed to help educate international travelers.

The web address of U.S. Customs and Border Protection is <http://www.cbp.gov>

Customs Regulations

The current edition of *Customs Regulations of the United States* is a loose-leaf, subscription publication available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402; telephone (202) 512-1800. A bound, 2003 edition of Title 19, *Code of Federal Regulations*, which incorporates all changes to the Regulations as of April 1, 2003, is also available for sale from the same address. All proposed and final regulations are published in the *Federal Register*, which is published daily by the Office of the Federal Register, National Archives and Records Administration, and distributed by the Superintendent of Documents. Information about on-line access to the *Federal Register* may be obtained by calling (202) 512-1530 between 7 a.m. and 5 p.m. Eastern time. These notices are also published in the weekly *Customs Bulletin* described below.

Customs Bulletin

The *Customs Bulletin and Decisions* ("Customs Bulletin") is a weekly publication that contains decisions, rulings, regulatory proposals, notices and other information of interest to the trade community. It also contains decisions issued by the U.S. Court of International Trade, as well as customs-related decisions of the U.S. Court of Appeals for the Federal Circuit. Each year, the Government Printing Office publishes bound volumes of the *Customs Bulletin*. Subscriptions may be purchased from the Superintendent of Documents at the address and phone number listed above.

Importing Into the United States

This publication provides an overview of the importing process and contains general information about import requirements. The February 2002 edition of *Importing Into the United States* contains much new and revised material brought about pursuant to the Customs Modernization Act ("Mod Act"). The Mod Act has fundamentally altered the relationship between importers and U.S. Customs and Border Protection by shifting to the importer the legal responsibility for declaring the value, classification, and rate of duty applicable to entered merchandise.

The February 2002 edition contains a section entitled "Informed Compliance." A key component of informed compliance is the shared responsibility between U.S. Customs and Border Protection and the import community, wherein CBP communicates its requirements to the importer, and the importer, in turn, uses reasonable care to assure that CBP is provided accurate and timely data pertaining to his or her importation.

Single copies may be obtained from local offices of U.S. Customs and Border Protection, or from the Office of Public Affairs, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Washington, DC 20229. An on-line version is available at the CBP web site. *Importing Into the United States* is also available for sale, in single copies or bulk orders, from the Superintendent of Documents by calling (202) 512-1800, or by mail from the Superintendent of Documents, Government Printing Office, P.O. Box 371954, Pittsburgh, PA 15250-7054.

Informed Compliance Publications

U.S. Customs and Border Protection has prepared a number of Informed Compliance publications in the "*What Every Member of the Trade Community Should Know About:...*" series. Check the Internet web site <http://www.cbp.gov> for current publications.

Value Publications

Customs Valuation under the Trade Agreements Act of 1979 is a 96-page book containing a detailed narrative description of the customs valuation system, the customs valuation title of the Trade Agreements Act (§402 of the Tariff Act of 1930, as amended by the Trade Agreements Act of 1979 (19 U.S.C. §1401a)), the Statement of Administrative Action which was sent to the U.S. Congress in conjunction with the TAA, regulations (19 C.F.R. §§152.000-152.108) implementing the valuation system (a few sections of the regulations have been amended subsequent to the publication of the book) and questions and answers concerning the valuation system. A copy may be obtained from U.S. Customs and Border Protection, Office of Regulations and Rulings, Value Branch, 1300 Pennsylvania Avenue, NW, (Mint Annex), Washington, D.C. 20229.

Customs Valuation Encyclopedia (with updates) is comprised of relevant statutory provisions, CBP Regulations implementing the statute, portions of the Customs Valuation Code, judicial precedent, and administrative rulings involving application of valuation law. A copy may be purchased for a nominal charge from the Superintendent of Documents, Government Printing Office, P.O. Box 371954, Pittsburgh, PA 15250-7054. This publication is also available on the Internet web site of U.S. Customs and Border Protection.

The information provided in this publication is for general information purposes only. Recognizing that many complicated factors may be involved in customs issues, an importer may wish to obtain a ruling under CBP Regulations, 19 C.F.R. Part 177, or obtain advice from an expert (such as a licensed Customs Broker, attorney or consultant) who specializes in customs matters. Reliance solely on the general information in this pamphlet may not be considered reasonable care.

Additional information may also be obtained from U.S. Customs and Border Protection ports of entry. Please consult your telephone directory for an office near you. The listing will be found under U.S. Government, Department of Homeland Security.

“Your Comments are Important”

The Small Business and Regulatory Enforcement Ombudsman and 10 regional Fairness Boards were established to receive comments from small businesses about Federal agency enforcement activities and rate each agency’s responsiveness to small business. If you wish to comment on the enforcement actions of U.S. Customs and Border Protection, call 1-888-REG-FAIR (1-888-734-3247).

REPORT SMUGGLING 1-800-BE-ALERT OR 1-800-NO-DROGA



Visit our Internet web site: <http://www.cbp.gov>